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August 31, 2020

VIA CM/ECF

The Honorable Maryellen Noreika
United States District Court for the District of Delaware
844 N. King Street
Wilmington, DE 19801

Re: *Biogen International GmbH et al. v. Amneal Pharmaceuticals LLC, et al.*,
C.A. No. 17-823-MN (Consolidated)

Dear Judge Noreika:

I write on behalf of Defendants MSN, Hetero, and Shilpa (“Defendants”) to follow up with the Court regarding Mylan’s launch of its generic dimethyl fumarate drug product (the “Mylan product”) and the resulting prejudice to Defendants while they remain off the market and subject to the current regulatory stay of approval.

Like Mylan, Defendants were among the group of first-filers to submit their ANDAs to FDA and challenge the now-invalidated ’514 patent. Thus, under Hatch-Waxman’s incentivized framework for first-filers, each of the Defendants has the opportunity to enjoy the same statutorily mandated 180-day period of market exclusivity with Mylan. As provided in our August 19, 2020 letter, Mylan launched the Mylan product, which started the 180-day exclusivity period for *all* first filers, including Defendants. Defendants have obtained tentative approval for their ANDAs, and thus but for the current regulatory stay, would be able to likewise launch their generic drug products. With every passing day that Defendants are unable to enter the market, they are losing the benefits of this exclusivity period and this is severely prejudicing them.

Defendants remain mindful of the Court’s extremely busy docket. However, due to the severe prejudice Defendants are facing, they respectfully request that the Court issue its ruling as soon as possible.

Respectfully submitted,

/s/ John C. Phillips, Jr.

John C. Phillips, Jr. (#110)

cc: All Counsel of Record (via electronic mail)